STATE OF MICHIGAN

IN THE SUPREME COURT

STATE OF MICHIGAN, ex rel. MARCIA GURGANUS,

Plaintiff-Appellee,

V

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN, LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDING CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & CO.; RITE AID OF MICHIGAN, INC.; PERRY DRUG STORES, INC.; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; and WAL-MART STORES, INC.,

Defendants-Appellants.

CITY OF LANSING and DICKINSON PRESS, INC.,

Plaintiffs-Appellees,

v

RITE AID OF MICHIGAN, INC. and PERRY DRUG STORES, INC.,

Defendants-Appellants.

Supreme Court Case No. 146791

Court of Appeals Case No. 299997

Kent County Circuit Court Case No. 09-03411-CZ

Hon, James R. Redford

AMICUS CURIAE BRIEF OF MICHIGAN CHAMBER LITIGATION CENTER



Supreme Court Case No. 146792

Court of Appeals Case No. 299998

Kent County Circuit Court Case No. 09-07827-CZ

Hon, James R, Redford

CITY OF LANSING, DICKINSON PRESS, INC., and SCOTT MURPHY, individually and on behalf of all others similarly situated,

Plaintiffs-Appellees,

v

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN, LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION: SEARS HOLDING CORPORATION: SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & COMPANY; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; and WAL-MART STORES, INC.,

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Hon. James R. Redford

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TABLE OF CONTENTS

	<u>rage</u>
TABLE OF	AUTHORITIESii
BASIS OF J	URISDICTIONiv
QUESTION	S PRESENTED FOR REVIEWiv
STATEMEN	TT OF INTEREST OF AMICUS CURIAE
INTRODUC	TION
BACKGROU	JND4
STANDARD	OF REVIEW6
ARGUMENT	Γ7
I.	The Court should reject the concept of implied certification or implied representation that the Court of Appeals imported into Michigan's false claims acts
II.	The Court of Appeals' implied-legal-falsity standard eliminates Michigan's false claims acts' scienter standard that requires plaintiffs to prove that a defendant knowingly submitted a false claim
III.	If the Court does not reject "implied certification" altogether, the theory should be strictly limited it to statutes and regulations on which payment is expressly conditioned
IV.	The Court of Appeals' decision threatens to raise healthcare costs and stifle Michigan's growing healthcare industry, which currently employs nearly one-fifth of Michigan's workforce
CONCLUSIO	N14

TABLE OF AUTHORITIES

<u>Page</u>	<u>(s)</u>
State Cases	
Adams Outdoor Advertising v City of East Lansing, 463 Mich 17; 614 NW2d 634 (2000)	10
<i>Driver v Naini</i> , 490 Mich 239; 802 NW2d 311 (2011)	. 7
In re Wayne County Prosecutor, 121 Mich App 798; 329 NW2d 510 (1983)	. 8
People v Williamson, 205 Mich App 592; 517 NW2d 846 (1994)	. 8
Spectrum Health Hospital v Farm Bureau Mutual Insurance Co of Michigan, 492 Mich 503; 821 NW2d 117 (2012)	. 6
Federal Cases	
Ebeid ex rel United States v Lungwitz, 616 F3d 993 (CA 9, 2010)	9
Mikes v Straus, 274 F3d 687 (CA 2, 2001)	4
Siewick v Jamieson Science & Engineering, Inc, 214 F3d 1372 (CA DC, 2000)	2
United States ex rel Hobbs v MedQuest Associates, Inc, 711 F3d 707 (CA 6, 2013)	9
United States ex rel Hutcheson v Blackstone Medical, Inc, 647 F3d 377 (CA 1, 2011)	9
United States ex rel Yannacopoulos v Gen Dynamics, 652 F3d 818 (CA 7, 2011)	
State Statutes	
MCL 333.1101	4
MCL 333.17755	5
MCL 333.17768	3
NACT 222 0700	

$\underline{Page(s)}$
MCL 400.601
MCL 400.602
MCL 400.603
MCL 400.607
MCL 400.61213
MCL 752.1001
MCL 752.1002
MCL 752.1003
Federal Statutes
31 USC 3729 8
State Rules
MAC R 338.497
MCR 2.116
MCR 7.301iv
Other Authorities
1 John T Boese, Civil False Claims and Qui Tam Actions (4th ed)
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BASIS OF JURISDICTION

This Court has jurisdiction under MCR 7.301(A)(2) because the Defendant Pharmacies are appealing a final order of the Court of Appeals.

QUESTIONS PRESENTED FOR REVIEW

In its order granting leave to appeal, the Court asked the parties to address seven issues.

The Michigan Chamber Litigation Center submits this brief to address the error of the Court of Appeals the Chamber believes will have the most deleterious effect on Michigan law.

1. Under the Michigan False Claims Act ("MFCA") and the Health Care False Claims Act ("HCFCA"), anyone who submits a claim to Medicaid or other health insurers "knowing the claim to be false" has committed a felony and, under the MFCA, is civilly liable for no less than \$5,000 and treble damages. Does a claim that fails to comply with the Public Health Code inherently violate the MFCA and HCFCA as a "false claim"?

The trial court did not answer.

The Court of Appeals answered: Yes.

Plaintiffs-Appellees answer: Yes.

Defendant-Appellant Pharmacy Owners answer: No.

Amicus Curiae answers: No.

STATEMENT OF INTEREST OF AMICUS CURIAE

The Michigan Chamber of Commerce is Michigan's largest business federation. It represents the interests of over 6,800 businesses engaged in commercial, industrial, agricultural, civic, and professional activities across the State of Michigan, as well as local chambers of commerce and trade and professional associations. Members include businesses of every size and type and come from every one of the State's 83 counties, representing a broad cross section of the State's economy. The Chamber's mission is to promote conditions favorable to job creation and business growth in Michigan. Its vision is to move Michigan forward through economic, political, and social systems based on individual freedom, incentive, opportunity, and responsibility. A principal function of the Chamber and the Michigan Chamber Litigation Center is to represent the interests of its members by filing *amicus curiae* briefs in cases of vital concern to the State's business community.

Like the defendants in these cases, many of the Chamber's members provide healthcare services. Compliance with health care statutes, rules, and regulations is vitally important, and the Chamber's members who provide healthcare services dedicate significant resources each year to internal compliance programs that complement the government's and health insurer's efforts to prevent misconduct. The Chamber supports appropriate enforcement of Michigan's false claims acts. At the same time, a balance must be maintained between enforcement and preventing vexatious and unnecessary litigation that does not serve the Act's purposes.

The Chamber is keenly interested in the Court's determination of the issues presented in these consolidated cases because the Court of Appeals did not maintain that balance. Instead, the court adopted a test for implied certification of claims under which non-compliance with any of the myriad healthcare rules and regulations could result in a judgment imposing significant

liability, up to and including treble damages. Further, the Court of Appeals' expansion of antifraud statutes into a vehicle for private enforcement of healthcare regulations threatens the Chamber's mission of promoting conditions that are favorable to job creation and business growth in Michigan. Specifically, the increased risk to healthcare-service providers throughout the State will cause an increase in medical and health-insurance costs by increasing the number of exorbitantly expensive false-claims cases at a time when changes in federal law are already driving up health care costs.

INTRODUCTION

These cases present an issue of profound interest to every Michigan healthcare provider and professional, in addition to millions of Michigan consumers of healthcare services and prescription drugs. Under Michigan's Medicaid False Claims Act ("MFCA") and Health Care False Claims Act ("HCFCA"), anyone who submits a claim to Medicaid or other healthcare insurers "knowing the claim to be false," is guilty of a felony punishable by up to four years in prison and a \$50,000 fine, and civilly liable for no less than \$5,000 per violation plus treble damages. The prototypical false claims acts lawsuit alleges that the defendant submitted a factually false claim—a request for payment for goods or services that were not provided as claimed. In recent years, the federal False Claims Act has been expanded by some courts to impose liability in some instances for legal falsity. Such claims assert that by submitting a claim for payment, a defendant certifies that it has complied with governing statutory, regulatory, contractual or other conditions of payment. If some condition of payment was not met, the certification is deemed legally false even if the goods or services were provided as claimed. The Michigan false claim acts refer only to factually false claims and do not identify legally false claims as actionable.

Plaintiffs allege that the defendant pharmacy owners violated the MFCA and HCFCA in thousands of drug sales by failing to comply with a statute requiring "pharmacists" to "pass on" the wholesale cost savings of substituting a generic prescription drug for its brand-name equivalent (the "Substitution Statute"). Plaintiffs do not contend that the Defendants did not provide pharmaceutical products as claimed. Nonetheless, the Court of Appeals held that every claim failing to comply with the Substitution Statute was "false," because every claim "impliedly

represents" compliance with the Substitution Statute. The Court of Appeals gave no reason for reading the concept of legal falsity and implied certification into the MFCA or HCFCA.

The court's judicial expansion of Michigan's false claims acts threatens serious harm to Michigan's healthcare industry, and its economy as a whole. The Court of Appeals' conclusion cannot be easily confined to claims for payments for prescription drugs. To the contrary, the court's reasoning that a healthcare claim for payment impliedly represents compliance with Michigan statutes, rules, and regulations governing the provision of healthcare exposes companies, professionals, and even consumers to felony convictions, harsh civil penalties, and treble damages for every technical violation of the Public Health Code. Further, the Court of Appeals' reasoning relieves plaintiffs of their statutory burden to prove that a misleading "statement of fact" was knowingly submitted.

BACKGROUND

The facts and procedural background relevant to the legal issues presented in this *amicus* curiae brief are as follows:

1. Healthcare in Michigan is governed by the Public Health Code, MCL 333.1101 et seq. The breadth of the Code is extensive. It regulates most, if not all, actors in the healthcare industry: hospitals, pharmacies, healthcare professionals, laboratories, outpatient facilities, nursing homes, ambulances, and so forth. It also regulates nearly all aspects of the industry in great detail, with specific rules and regulations covering, for instance, childbirth, record keeping, emergency medical services, nutrition, anatomical gifting, licensing, drug manufacturing, and prescription drug purchases.

- 2. The claims at issue in this case are all based on a special provision in Michigan's Public Health Code addressing substitution of a generic drug for its brand-name equivalent. The Substitution Statute states:
 - (1) When a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy, except as provided in subsection (3). If a drug is dispensed which is not the prescribed brand, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed, except as otherwise provided in section 17756.
 - (2) If a pharmacist dispenses a generically equivalent drug product, the pharmacist shall pass on the savings in cost to the purchaser or to the third party payment source if the prescription purchase is covered by a third party pay contract. The savings in cost is the difference between the wholesale cost to the pharmacist of the 2 drug products.
 - (3) The pharmacist shall not dispense a generically equivalent drug product under subsection (1) if any of the following applies:
 - (a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his or her own handwriting "dispense as written" or "d.a.w." on the prescription.
 - (b) The prescriber, having preprinted on his or her prescription blanks the statement "another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed d.a.w.", writes in his or her own handwriting, the initials "d.a.w." in a space, box, or square adjacent to the statement.
 - (c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated.
 - (4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser.

MCL 333.17755. The Substitution Statute has not been revised since it became effective in 1978.

- 3. Three sets of plaintiffs filed three separate original actions in circuit court against various pharmacy owners for violating the Public Health Code. Marcia Gurganus filed her complaint as a *qui tam* relator, alleging violations of MCL 333.17755(2) as a basis for liability under the MFCA, MCL 400.601 *et seq*. The two putative class actions alleged, among other things, violations of MCL 333.17755(2) as a basis for liability under the HCFCA, MCL 752.1001 *et seq*. The circuit court dismissed the complaints under MCR 2.116(C)(8).
- 4. In response to Plaintiffs' appeal (as well as in the trial court), the pharmacy owners argued that Plaintiffs failed to plead a violation of the MFCA and HCFCA because the alleged violation of the Substitution Statute did not constitute a "false claim" within the meaning of the MFCA and the HCFCA. Plaintiffs responded by arguing that a claim violating the Substitution Statute is a "false claim."
- 5. In reversing the circuit court, the Court of Appeals held that a claim for payment for a generic drug that is not consistent with the Substitution Statute is a "false claim" because every such claim contains an implicit false certification of compliance. (COA Op 20.) In the court's words, "defendants' presentation of claims for payment **impliedly represents** to purchasers and payees that defendants are passing on the savings in cost, if any, when generic drugs are dispensed." (*Id.* (emphasis added).)

STANDARD OF REVIEW

The questions presented in this *amicus curiae* brief are issues of law, which this Court reviews de novo. See *Spectrum Health Hosp v Farm Bureau Mut Ins Co of Mich*, 492 Mich 503, 515; 821 NW2d 117 (2012).

ARGUMENT

I. The Court should reject the concept of implied certification or implied representation that the Court of Appeals imported into Michigan's false claims acts.

The Court of Appeals' decision significantly expands the range of conduct criminalized by the Michigan false claims act by construing the act to prohibit the submission of claims for health care products and services that do not fully comply with Michigan's myriad healthcare rules and regulations. Even though the false claims acts specifically identify factual inaccuracies and omissions as prohibited conduct, the Court of Appeals ruled that the Plaintiffs could proceed in their cases because the pharmacy defendants "impliedly represent[ed]" compliance with the Substitution Statute. There is no foundation in the text of the false claims acts for punishing implied legal falsity.

Interpreting the meaning of a statute is primarily a matter of examining the statute's plain language, *Driver v Naini*, 490 Mich 239, 246–247; 802 NW2d 311 (2011). Under the MFCA and the HCFCA, it is a felony to "make or present or cause to be made or presented . . . a claim . . . knowing the claim to be false." MCL 400.607; MCL 752.1003(1). Both statutes define "false" as "wholly or partially untrue or deceptive." MCL 400.602(d); MCL 752.1002(c). Both statutes contain a similar definition of "deceptive." Under the MFCA:

"Deceptive" means making a claim or causing a claim to be made under the social welfare act that contains a statement of fact or that fails to reveal a fact, which statement or failure leads the department to believe the represented or suggested state of affair to be other than it actually is.

MCL 400.602(c). And under the HCFCA:

"Deceptive" means making a claim to a health care corporation or health care insurer which contains a statement of fact or which fails to reveal a material fact, which statement or failure leads the health care corporation or health care insurer to believe the represented or suggested state of affair to be other than it actually is.

MCL 752.1002(b). Thus, under both statutes, a claim is "deceptive" if it "contains" a statement of fact or fails to reveal a fact that will lead the healthcare insurer or the Department "to believe the represented or suggested state of affair to be other than it actually is."

The statutory language addresses the prototypical false claim—a request for payment for goods or services that were not provided as claimed. See, e.g., *In re Wayne Co Prosecutor*, 121 Mich App 798, 802; 329 NW2d 510 (1983); *People v Williamson*, 205 Mich App 592, 593–595; 517 NW2d 846 (1994). There is not anything factually untrue in a claim seeking a particular price for services actually rendered or products actually provided, even if that price is incorrect as a matter of law.

The implied false-certification theory that has been adopted by some federal courts has an arguable connection to the text of the federal False Claims Act. The federal statute punishes making "false or fraudulent claim[s]" and does not define "false" or "fraudulent." 31 USC 3729(a)(1). Thus, the federal statute does not limit false claims to factual inaccuracies and omissions. Contra MCL 400.602(c), 752.1002(b). The expansion of the federal False Claims Act to punish implied legal falsity has generated confusion and division among the federal courts. Some courts have not adopted implied certification entirely. E.g., *United States ex rel Yannacopoulos v Gen Dynamics*, 652 F3d 818, 824 n 4 (CA 7, 2011) (requiring express certification of compliance with law or regulation to state a false claim). Others, including the

¹ "Represented" is the past tense transitive verb form of "representation," a legal term of art meaning a "presentation of fact—either by words or by conduct." Black's Law Dictionary (2d Pocket Ed, 2001). "Suggested" is the past tense of "suggest" which is to "put forward for consideration"; "cause one to think that (something) exists or is the case"; or "state or express indirectly." The Oxford American College Dictionary (2002). Finally, a "state of affairs" is a "situation or set of circumstances." *Id*.

Sixth Circuit, limit the implied-certification theory to instances where the underlying statute, regulation or contract expressly condition payment upon compliance. E.g., *United States ex rel Hobbs v MedQuest Assocs, Inc*, 711 F3d 707, 713-714 (CA 6, 2013); *Ebeid ex rel United States v Lungwitz*, 616 F3d 993, 997-998 (CA 9, 2010). Other federal courts have adopted an implied-certification theory that implies certification of compliance with any statute, regulation, or contract language that is material to payment. E.g., *United States ex rel Hutcheson v Blackstone Medical, Inc*, 647 F3d 377, 387-388 (CA 1, 2011).

Here, the Court of Appeals adopted an especially expansive version of the theory of implied certification. The Court held that by submitting a claim for reimbursement for generic prescription drugs, the pharmacy owners "impliedly represent[ed] to purchasers and payees" that they were "passing on the savings in cost, if any, when generic drugs are dispensed." (COA Op 20.) In other words, the Court of Appeals reasoned that any time a pharmacy submits a bill for generic prescription drugs, it is impliedly certifying compliance with the Substitution Statute. The court did not limit liability for legal falsity to instances where a defendant actually certifies compliance with a given contractual or statutory condition of compliance. Instead, the court concluded that by submitting a claim for payment, the defendant "impliedly represents" compliance with the Substitution Statute and, presumably, all other healthcare statutes and regulations.

This implied-representation or implied-certification theory finds no basis in the texts of Michigan's false claims acts and runs contrary to their plain language. Nothing in the Michigan statutes imposes liability based on an "implied" certification of compliance with the law. The statutes state that a claim is deceptive when it contains a "statement of fact" that misleads the government or private health insurer. MCL 400.602(c); MCL 752.1002(b). The statutes do not

authorize the court to establish liability based on a statement of legal opinion, nor do they impose liability for statements not actually made but instead inferred by the court as a matter of law. Moreover, the divisions among the federal courts demonstrate the difficulty of applying an implied-certification theory even when the statutory text allows for it—as Michigan statutes do not. Accordingly, the Court of Appeals should be reversed.

II. The Court of Appeals' implied-legal-falsity standard eliminates Michigan's false claims acts' scienter standard that requires plaintiffs to prove that a defendant knowingly submitted a false claim.

The Court of Appeals' theory should be rejected because it eliminates the false claims statutes' scienter requirement, contrary to the Legislature's intent. Under the false claims statutes, plaintiffs must show that defendants submitted a claim "knowing the claim to be false." MCL 400.607; MCL 752.1003(1). If a defendant does not know of the statement of fact in its claim, or was mistaken about the factual circumstances surrounding its claim, then ignorance (including by mere negligence) would be a complete defense.

Implying certification of legal compliance, however, relieves plaintiffs of their statutory burden to prove the defendant actually submitted a false claim "knowing the claim to be false."

1 John T Boese, Civil False Claims and *Qui Tam* Actions (4th ed), § 2.03[G], at 2-189 (explaining that the implied certification theory has a similar effect under the federal False Claims Act).

Because knowledge of the law is presumed, *Adams Outdoor Advertising v City of East Lansing*, 463 Mich 17, 27 n 7; 614 NW2d 634, 640 (2000), the defendant would be presumed to know that it had made an implied certification and that its claim was not in compliance, i.e., "legally false," see *Mikes v Straus*, 274 F3d 687, 696–697 (CA 2, 2001) (discussing legally false certification theory under the federal false claims act). Taking the Court of Appeals' theory to its logical con-

clusion, the plaintiff's burden would now be limited to proving the defendant violated regulations. Proving scienter is not necessary for the Court of Appeals' expansive theory of legally false claims.

Rather than furthering the Michigan false claims acts' purpose of stamping out fraud, the Court of Appeals' judicial gloss transforms the acts into "blunt instruments" for punishing businesses and individuals who mistakenly fail to comply with regulatory requirements before submitting a claim. See *Mikes*, 274 F3d at 699. Take for instance, the requirement to obtain approval from Medicaid before prescribing drugs that are not on the preferred drug list. MCL 333.9709. An inadvertent failure to obtain prior approval is benign and easily corrected through Medicaid's own administrative process by, for example, denying the claim. But under the lower court's implied-certification theory, it would be a violation of the false claims acts, punishable by up to four years of imprisonment, a criminal fine of \$50,000, an award of treble damages, and a minimum civil penalty of \$5,000. The plain language of the false claims acts prohibits this result by requiring the knowing submission of a factually false claim. For this additional reason, the Court of Appeals' implied-certification standard should be rejected.

III. If the Court does not reject "implied certification" altogether, the theory should be strictly limited it to statutes and regulations on which payment is expressly conditioned.

If implied certification is to be accepted despite the absence of a bases in the text of the false claim acts, the Court should limit the doctrine to implied certification of compliance with statutes and regulations that condition payment on compliance as federal courts have done in the context of the federal False Claims Act. As the Second Circuit explained in *Mikes*, the concept of implied certification "does not fit comfortably into the health care context because the federal False Claims Act was not designed for use as a blunt instrument to enforce compliance with all

medical regulations—but rather only those regulations that are a precondition to payment—and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach." 274 F3d at 699. Accordingly, the court held that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid," and only "when a defendant submits a claim for reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant." *Id.* at 700. At the very least, these same limitations should be imposed here.

To start, federal courts "have been ready to infer certification from silence . . . only where certification was a prerequisite to the government action sought." See Siewick v Jamieson Science & Eng'g, Inc, 214 F3d 1372, 1376 (CA DC, 2000). This makes the implication one of fact rather than law. While it still stretches the statutory language to imply a "statement of fact" when an actual statement is required under the statute, at least the implication would arise only in limited circumstances where the defendant can readily know that certification is implied.

Second, even when the risk of an inference should be readily apparent, the plaintiff should still be required to prove that the defendant knew when it submitted the claim that payment was expressly precluded because of a failure of the defendant to comply with regulations. Because the consequences for violating the false claims acts can be severe, the Legislature required a high level of culpability—knowledge—for the defendant to be held liable or guilty. The statute was not designed to imprison or financially ruin those who unwittingly or even carelessly make a claim while inadvertently failing to comply with regulatory or contractual requirements.

IV. The Court of Appeals' decision threatens to raise healthcare costs and stifle Michigan's growing healthcare industry, which currently employs nearly one-fifth of Michigan's workforce.

Superimposing the harsh criminal penalties and civil liability of the false claims acts onto ordinary violations of the Public Health Code will have serious deleterious effects on Michigan's growing healthcare industry and its economy as a whole. Practically every healthcare business and professional and most Michigan residents rely on private health insurers or the government to some extent for the payment of healthcare services and products. Payment for these services and products comprises a surprisingly large share of Michigan's economy. The World Health Organization reports that the U.S. expenditure on healthcare as a percent of gross domestic product was 15.2% in the year 2000. But "Midwesterners spend more on health care related expenditures, as a proportion of total spending, than any other region in the country." Michigan Workforce Development Agency, *Health Care Cluster Workforce Analysis*, 2 (Jan 2013). The healthcare industry "accounts for nearly 18% of total employment in Michigan." *Id.* Thus, nearly one-fifth of Michigan's workforce is employed in the healthcare industry.

By making liability under the false claims acts arise automatically for failure to comply with healthcare regulations, the Court of Appeals has dramatically increased the financial and personal risks of investing or participating in the healthcare industry. Under the Public Health Code, the sort of generic violation at issue here would at worst result in a fine of no more than \$5,000, revocation of a license, and an order of restitution from the Board of Pharmacy. MCL 333.17768; MAC R 338.497. By contrast, a defendant who violates the MFCA and HCFCA is guilty of a felony, may serve up to four years in prison, and be fined up to \$50,000. MCL 400.603(4); MCL 752.1003(5). In addition, each violation of the MFCA subjects the defendant to a civil penalty no less than \$5,000, and up to \$10,000, plus treble damages. MCL 400.612.

The "implied certification" theory also invites a wave of litigation against healthcare businesses and professionals in Michigan, for the benefit of class-action plaintiffs and their attorneys eager to share in the bonanza created by the Court of Appeals' decision. It is far easier to prove some technical violation of one of the many healthcare and Medicaid regulations than it is to prove a business or individual knowingly made a false or misleading representation of fact. Although this particular case concerns violations of a specific provision in the Public Health Code relating to pharmacies, the Court of Appeals' analysis necessarily goes further than that. It implicates nearly every healthcare regulation which the State or a health insurer could argue was material to its decision to pay. Every medical regulation and every standard of care dictating how medical services should be provided, how drugs should be dispensed, or how medical equipment should be sold could conceivably be material to a third-party insurer's willingness to pay for that service, drug, or equipment. See *Mikes*, 274 F3d at 699—700 (refusing to apply a broad "implied certification" theory because it would federalize medical malpractice).

The increased exposure to litigation and to severe civil and criminal penalties resulting from the lower court's decision can only drive up the cost of drugs, medical care, and medical insurance in Michigan. The Court of Appeals' decision, if unreversed, will discourage future investment and potentially drive healthcare professionals out of the state. The inevitable effect of this will be both a scarcity of services and products and an increase in the cost for healthcare. The Court should reverse the Court of Appeals' decision.

CONCLUSION

For the reasons given above, the Court should reverse the Court of Appeals and affirm the circuit court's decision granting summary disposition in favor of the defendants.

Respectfully submitted,

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